AMENDMENTS TO THE CLAIMS

Please amend claims 1, 11, 18 and 31 as indicated below.

Please cancel claims 21-24 and 27-30 without prejudice.

Please add new claims 32-34.

A complete list of claims as currently amended follows:

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core consisting essentially of metfomin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient.

(b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core; and

(c) an immediate release thiazolidinedione derivative containing coat applied to the primary seal coat wherein the thiazolidinedione derivative is ~~troglitazone, rosiglitazone~~, pioglitazone~~, ciglitazone~~ or pharmaceutically acceptable salts~~, isomers or derivatives~~ thereof and wherein the dosage form exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours and not less than 75% of the pioglitazone is released after 30 minutes.

2. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.

3. (previously presented) The dosage form of claim 2 wherein the osmotic tablet consists essentially of:

(a) a core consisting essentially of:

(i) 50-98% of said metformin or a pharmaceutically acceptable salt thereof;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally a secondary seal coat surrounding the core; and

(c) a semipermeable membrane consisting essentially of:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin or a pharmaceutically acceptable salt thereof.

4. (previously presented) The dosage form of claim 1 wherein said metformin or a pharmaceutically acceptable salt thereof is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.

5. (canceled).

6. (canceled).

7. (previously presented) The dosage form of claim 1 wherein the release of the metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.

8. (previously presented) The dosage form of claim 1 wherein said controlled release of said metformin or a pharmaceutically acceptable salt thereof provides a Tmax of 8-12 hours.

9. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.

10. (original) The dosage form of claim 9 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.

11. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core consisting essentially of metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient;

(b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core; and

(c) an immediate release thiazolidinedione derivative containing coat applied to the primary seal coat comprising:

(i) a thiazolidinedione derivative; and

(ii) a binder;

wherein the immediate release coat is applied to the primary seal coat using a solvent mixture comprising water and an organic solvent and wherein the thiazolidinedione derivative is ~~troglitazone, rosiglitazone,~~ pioglitazone~~,~~ ~~ciglitazone~~ or pharmaceutically acceptable salts~~, isomers or derivatives~~ thereof and wherein the dosage form exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours and not less than 75% of the pioglitazone is released after 30 minutes .

12. (original) The dosage form of claim 11 wherein said controlled release core is an osmotic tablet.

13. (previously presented) The dosage form of claim 12 wherein the osmotic tablet consists essentially of:

(a) a core consisting essentially of:

(i) 50-98% of said metformin or a pharmaceutically acceptable salt thereof;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally a secondary seal coat surrounding the core; and

(c) a semipermeable membrane consisting essentially of:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer; and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin or a pharmaceutically acceptable salt thereof.

14. (previously presented) The dosage form of claim 11 wherein said metformin or a pharmaceutically acceptable salt thereof is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
15. (canceled).
16. (canceled).
17. (previously presented). The dosage form of claim 11 wherein the release of the metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.
18. (currently amended) The dosage form of claim 11 wherein said controlled release of said metformin or a pharmaceutically acceptable salt ~~therof~~ thereof provides a Tmax of 8-12 hours.
19. (original) The dosage form of claim 11 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
20. (original) The dosage form of claim 19 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
21. (canceled).
22. (canceled).
23. (canceled).
24. (canceled).
25. (canceled).
26. (canceled).
27. (canceled).
28. (canceled).
29. (canceled).
30. (canceled).
31. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form consisting essentially of:

(a) an osmotic tablet core wherein the osmotic tablet core consists essentially of:

(i) a core consisting essentially of:

(I) 50-98% of metformin or a pharmaceutically acceptable salt thereof;

(II) 0.1-40% of a binding agent; and

(III) 0-20% of an absorption enhancer;

(ii) optionally a secondary seal coat surrounding the core; and

(iii) a semipermeable membrane consisting essentially of:

(I) 50-99% of a polymer;

(II) 0-40% of a flux enhancer and

(III) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin;

(b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the osmotic tablet core

(c) an immediate release thiazolidinedione derivative containing coat consisting essentially of :

(i) pioglitazone[[,]] or pharmaceutically acceptable salts~~, isomers or derivatives~~ thereof; and

(ii) a binder

wherein the immediate release coat is applied to the primary seal coat that is applied to the osmotic tablet core using a solvent mixture comprising water and an organic solvent and wherein the dosage form provides a Tmax of 8-12 hours for the metformin and a Tmax of 1-4 hours for the pioglitazone and wherein the dosage form exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours and not less than 75% of the pioglitazone is released after 30 minutes.

32. (new) The pharmaceutical dosage form of claim 1 wherein the immediate release thiazolidinedione coat comprises:

(i) pioglitazone or a pharmaceutically acceptable salt;
(ii) a binder;
(iii) a surfactant; and
(iv) a pore former; and
wherein the immediate release coat is applied to the primary seal coat using water, an organic solvent or a solvent mixture comprising water and an organic solvent.

33. (new) The pharmaceutical dosage form of claim 1 wherein at least 79% of the pioglitazone is release from the dosage form after 20 minutes of testing in a USP apparatus type 1 at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution.

34. (new) The pharmaceutical dosage form of claim 1 wherein at least 95% of the pioglitazone is release from the dosage form after 30 minutes of testing in a USP apparatus type 1 at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution.